REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested. Claims 1, 2, 4, and 6-8 are pending. Amendments have been made solely for clarification and without acquiescing to any rejection raised in the Action. No new matter has been added to the application. Support for the amendments may be found throughout the specification. As an initial matter Applicants thank the Examiner for her kind teleconference on November 21, 2003, wherein all outstanding issues were discussed. The claims have been amended, without acquiescence, to respond to the concerns raised.

Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1, 2, 4, and 6-8 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabling one of skill in the art to practice the claimed invention. As an initial matter, the Action suggests amending dependent claims 2, 4 and 6-8 to recite "The method according to claim..." rather than "A method according to claim...". Applicants wish to thank the Examiner for pointing out this discrepancy, and have amended the claims for clarification. With regard to the enablement rejection, the Action alleges the phrase "one or more antigenic components" is broader in scope than the written description in the instant specification for the claimed invention.

Applicants respectfully traverse this ground for rejection and maintain the specification adequately supports the scope of the claims such that one of skill in the art is enabled to practice the claimed invention. The Action alleges Examples 1-5 do not provide adequate support for the genus encompassed by the phrase "one or more antigenic components." Applicants submit that while the working examples in the specification indicate aspects of the claimed invention, working examples of every aspect of the invention are not required to satisfy 35 U.S.C. § 112, first paragraph. *See In re Meir Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA, 1982). Additionally, if those skilled in the art can tell whether any particular embodiment is or is not within the scope of a claim, the claim fulfills its purpose as a definition. *See In re Miller, 441 F.2d 689, 169 U.S.P.Q. 597, 599 (CCPA 1971).* Furthermore, that

experimentation may be involved is not determinative of the question of scope of enablement; it is only undue experimentation that is fatal. See *In re Geerdes,* 491 F.2d 1260, 180 U.S.P.Q. 789, 793 (CCPA, 1974). Applicants submit that the amount of experimentation which may be required to practice the present invention does not rise to the level of being *undue* experimentation, as defined by the Court in *Wands*. See *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

An important aspect of the Court's decision in *Wands* is its finding that the nature of the technology pertinent to the Wands invention (monoclonal antibody production) permitted a *broad* definition of the term "experiment". The Court found that an "experiment" in the monoclonal antibody art consisted of the entire attempt to make a monoclonal antibody against a particular antigen. As described by the Court, the process entailed, "immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening for antibodies produced by the hybridomas for the desired characteristics." 8 U.S.P.Q. 2d at 1407. Thus, *Wands* supports the conclusion that in a complex field such as monoclonal antibody production, the entire attempt to achieve the desired result, from beginning to end, constitutes *one* experiment.

According to the Court, repetition of this whole experiment more than once does not constitute undue experimentation. As the Court indicated, practitioners in the art would be prepared to screen negative hybridomas in order to find a hybridoma making the desired antibody. 8 U.S.P.Q.2d at 1406. Thus, the fact that some aspects of the experiment as a whole will yield negative results does not mandate finding that the amount of experimentation to achieve a positive result is undue.

Applicants believe that the present case is analagous to *Wands*. As set forth in Applicants previous Amendment, filed April 2, 2003, the skilled artisan would readily appreciate in light of the instant specification how to determine the antigenic components of non-infectious *Coxiella burnetii* lacking therapeutic and/or prophylactic effect against IDDM. Furthermore, the skilled artisan would readily recognize the routine nature of determining the inoperative components of non-infectious *Coxiella burnetii*, particularly given the teachings in the instant specification (see

for example, Examples 1-5 where non-infectious *C. brunetii* is used to ameliorate IDDM which spontaneously develops in the NOD mouse model system).

The Action further alleges one of skill in the art would be forced to do undue experimentation in order to practice the presently claimed invention. Applicants traverse this allegation and note that several factors are to be considered in determining whether a disclosure would require undue experimentation: (1) quantity of experimentation necessary, (2) amount of direction or guidance presented, (3) presence or absence of working examples, (4) nature of the invention, (5) state of the art, (6) relative skill of those in the art, (7) predictability of the art and (8) breadth of the claims. *In re Forman*, 230 USPQ 546, 547, (Bd. Pat. App. & Int. 1986). Applicants submit applying these criteria to the presently claimed invention, where the amount of experimentation needed to practice the invention is low, sufficient guidance is presented in the specification—including several working examples--and the nature of the invention, state of the art, relative skill in the art, and predictability of the art are such that one of ordinary skill in the art could practice the claimed invention. In addition, the breadth of the claims is supported by the specification. Applicants submit the specification *as a whole* must be considered in determining whether the scope of enablement provided by the specification is commensurate with the scope of the claims (emphasis original). *See In re Moore*, 439 F.2d 1232, 1237, 169 USPQ 236, 341 (CCPA, 1971). Applicants submit the specification adequately describes and enables one of ordinary skill in the art to practice the claimed invention within the scope of the claims.

Finally, the Action alleges "conception cannot be achieved until reduction to practice has occurred." *See* page 5, lines 1-2. Applicants submit conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention," and reduction to practice is not required when the disclosure adequately enables one of skill in the art to practice the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 136, 1376, 231 USPQ (BNA) 81, 87 (Fed. Cir. 1986). The Action further cites *Genentech, Inc. v. Novo Nordisk A/S*, and alleges the specification—not the knowledge of one of skill in the art—that determines whether the claimed invention is enabled. Applicants submit the Federal Circuit in *Genentech* held that every aspect of a generic claim need not have been carried

out by an inventor, or exemplified in the specification. *See Genentech, Inc. v. Novo Nordisk A/S*, 42 USPQ2d (BNA) 1001, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The Federal Circuit went on to say undue experimentation is required when there is no disclosure of any specific starting material or of any conditions under which a process can be carried out, whereas omission of minor details does not cause a specification to fail to meet the enablement requirement. See Genentech, at 1366. Thus, Applicants submit since adequate written disclosure of the starting material (C. *burnetii*) is provided in the specification as well as the Cowden Declaration, one of skill in the art could practice the claimed invention. Therefore, reduction to practice of every aspect is not required to satisfy 35 U.S.C. § 112, first paragraph.

Nonetheless, solely for clarification and without acquiescing to the rejection, Applicants have amended the claims to remove the objected to language. Applicants submit one of skill in the art is fully enabled to practice the presently claimed invention upon review of the instant specification. Accordingly, Applicants respectfully request the rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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